REMARKS

Claims 1-12 and 14-17 are pending in this application. Claims 1, 2, 3, 4, 7, 9, 10, 14, 15, 16 and 17 are amended. Claims 1, 2, 3, 4 and 9 are amended for clarity as discussed herein. Claims 7, 10, 14, 15, 16 and 17 are amended to remove multiple dependencies and clarity. The amendment to the claims is fully supported by the specification as discussed below. Therefore, no new matter is introduced. Claim 13 is cancelled without prejudice or disclaimer. The Office Action is discussed below:

Election/Restriction:

Claims 1-17 (Group 1) has been elected. The examiner has withdrawn claims 18-22, as being drawn to the non-elected Group 2.

Claim Objection:

On page 3 of the Office Action, claims 7-17 are objected by the examiner allegedly as being in improper form because the claims are dependent from a multiple dependent claim. In response, applicants amend claims 7, 10, 14, 15, 16, and 17 to remove multiple dependencies and cancel claim 13 without prejudice or disclaimer. Regarding withdrawal of the elected claims 7-17 by the examiner, applicants point out that the examiner did not address the multiple dependent claims in the Office Action restriction requirement of February 2, 2007. Accordingly, applicants elected Restriction Group 1 (Claims 1-17), as set forth by the examiner. Amended claims 7, 10, 14, 15, 16, and 17 fall under the Restriction Group 1, as set forth by the examiner. Therefore, applicants request withdrawal of the objection to claims 7-17.

Indefiniteness Rejection:

On pages 4-5 of the Office Action, the examiner rejects claim 1-6 under 35 U.S.C. 112, second paragraph, allegedly as being indefinite and incomplete for omitting essential steps. According to the examiner, claim 1 and all dependent claims 2-6 recite no method steps therefore do not lead to stated method goal. Applicants respectfully disagree with the examiner, however, in order to expedite the prosecution, amend claim 1 for clarity to recite that the method includes the step of: "(a) treating the sample to

reduce an inhibitory effect of the sample on the diagnostic method" and "(b) performing at least one step of the diagnostic method in the presence of DNase." Support for the amendment can be found in the specification, see for example, page 2, lines 17-19, page 4, second paragraph, and paragraphs 3-6, and pages 5-6. For example, the sample can be treated with a variety of compounds/reagents including, but not limited to: non-ionic alkyl glucosides, which are most effective surfactants for extracting CT LPS from the samples and making it available for antibody detection (see page 5, lines 20-22, for example); Polyvinyl alcohol (PVA) and/or Polyvinyl pyrrolidone (PVP), which are effective blocking agents that coat the nitrocellulose membrane fibers and effectively block the membrane from binding other reagents, which in turn allow more reagent to be available for reaction at the capture line and resulting in a cleaner background for the dipstick test (see page 5, lines 28-31, for example); and/or with an oxidizing agent, for example H_2O_2, which neutralizes some of the inhibitory substance(s) in the samples by oxidation (see page 5, line 40, for example).

Regarding claims 2-6, the examiner asserts that the phrase "preferably" renders the claims indefinite. In response, applicants amend claims 2, 3 and 9 by deleting the term "preferably" and clarify that the term was used to indicate alternative features.

Withdrawal of the indefiniteness rejections is therefore solicited.

Anticipation and Obviousness Rejections:

On pages 4-5 of the Office Action, the examiner rejects claims 1 and 3 allegedly as being anticipated by Biswas *et al.* (1997, *Journal of Clinical Microbiology* 35, 1560-1564). The examiner believes that Biswas *et al.* teach a method for treatment of a human patient sample (cervical brush smears) (refers to page 1560 paragraph 1-3) for carrying out a diagnostic method on the sample for detection of an infectious agent (HPV-16 E5) (refers to page 1567 "Results section"), wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase, wherein the DNase is present in an amount of 5U in 10 μl (refers to "Materials and Methods").

Applicants respectfully disagree with the examiner and clarify the cited reference in order to assist the examiner in distinguishing the claimed invention. Biswas *et al.* disclosure relates to the detection of HPV-16 early gene transcription by RT-PCR. Cervical brush smears obtained from patients were analyzed. Before carrying out RT-PCR, the samples were incubated overnight with DNase I. RNA was then extracted with phenol-chloroform-isoamyl alcohol prior to ethanol precipitation with linear polyacrylamide as a carrier. As would be apparent to the skilled person, DNase I is removed from the RNA by this procedure. Consequently, the subsequent RT-PCR procedure disclosed in Biswas was not performed in the presence of DNase. Indeed, since RT-PCR involves the synthesis of DNA, it would be most undesirable for the RT-PCR procedure to be carried out in the presence of DNase. Consequently, there is no disclosure in Biswas *et al.* of carrying out a diagnostic method in the presence of DNase. Therefore, the subject matter of amended claim 1 is not anticipated by Biswas *et al.*

On pages 5-6 of the Office Action, the examiner rejects claim 1 under 35 U.S.C. 102(b) allegedly as being anticipated by MacDonald *et al.* (US Patent No. 5,716,793, February 1998). According to the examiner, MacDonald *et al.* teach a method for treatment of a human patient sample for carrying out a diagnostic method on the sample for detection of an infectious agent (Chlamydia), wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase (refers to abstract, column 8 lines 14-34, column 16 lines 55-65).

Applicants respectfully disagree with the examiner and provide the following in order to assist the examiner in distinguishing the claimed invention from the cited reference. Applicants clarify that Column 16, lines 55-65 of MacDonald *et al.* describes preparation of total RNA from conjunctival swab samples taken from monkeys challenged with Chlamydia. RNA was isolated from the swab samples. It is stated that the RNA preparation was extracted several times with phenol:chloroform, resuspended and treated extensively with DNase I. Thus, the RNA isolated from the conjunctival swab was treated with DNase, not an endocervical fluid sample or vaginal fluid sample.

There is also no disclosure that the DNase is retained when testing the RNA preparation for presence of Chlamydial RNA. Applicants clarify that Column 17, lines 1-16 of MacDonald *et al.* describes use of a DNA probe containing the 16S and 23S ribosomal RNA and flanking sequences excised from a chlamydial genomic plasmid clone. Presence of DNase I in hybridization assays using the probe would be most undesirable since this would be expected to digest the probe. Therefore, MacDonald *et al.* does not anticipate amended claim 1.

On pages 6-7 of the Office Action, the examiner rejects claims 1-2 under 35 U.S.C. 103(a) allegedly as being unpatentable over Biswas *et al.* (1997, *Journal of Clinical Microbiology* 35, 1560-1564) in view of Holt *et al.* (TWGDAM Validation May 2001 pgs. 66-67).

The examiner admits that Biswas does not teach DNase present in an amount of more than 0.5 μg/ml, preferably 0.5 to 100μg/ml. However, the examiner believes that Holt *et al.* teach partially degraded DNA samples from blood and saliva samples were prepared using 0.005 units/μl of DNase I.

Regarding claim 3, reciting the amount of the DNase more than 0.5μg/ml, preferably 0.5 to 100 μg/ml, the examiner asserts that, the differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. The examiner believes that it would have been *prima facie* obvious at the time the invention was made to modify the method of treatment in the presence of DNase as taught by Biswas *et al.* to optimize the amount of the DNase because Biswas *et al.* and Holt *et al.* teach treatment with DNase in bodily fluids.

Applicants respectfully disagree with the examiner and refer to above clarification and arguments regarding Biswas *et al.* Applicants indicate that Biswas *et al.* does not disclose performing a diagnostic method in the presence of DNase. Holt *et al.* does not rectify the deficiencies of Biswas *et al.* Accordingly, the combination of the cited disclosure of Biswas *et al.* and Holt *et al.* does not provide a method within the scope of

amended claim 1 or dependent claim 2. Withdrawal of the obviousness rejection is therefore solicited.

On pages 7-8 of the Office Action, the examiner rejects claims 1 and 4-6 under 35 U.S.C. 103(a) allegedly as being unpatentable over MacDonald *et al.* (US Patent No. 5,716,793, February 1998) in view of Switchenko *et al.* (US Patent No. 5,563,038, October 8, 1996).

The examiner admits that Macdonald *et al.* does not teach a method for preparation, which includes the step of treating the sample with an oxidizing agent, wherein the oxidizing agent is hydrogen peroxide (H_2O_2), wherein a working concentration of hydrogen peroxide is of 0.5% to 3% w/v.

The examiner states that Switchenko *et al.* teach a method for detecting the antigens in a clinical swab sample (Chlamydia) whereby the cell membrane components that are separated by solubilization with detergents such as oxidizing agent hydrogen peroxide can be reconstituted. According to the examiner, Switchenko *et al.* teach that antigens can be separated from cellular debris and biological fluids by detergents such as oxidizing agent hydrogen peroxide. The examiner believes that Switchenko *et al.* teach solubilization thereof can be accomplished in accordance with the present invention by incubation of the (Chlamydia) bacterial sample in the presence of a detergent such as oxidizing agent hydrogen peroxide as described above, usually in the concentration range of from about 0.01 to 1.0%, weight to volume. The examiner also believes that Switchenko *et al.* teach one aliquot was combined with sufficient H_2O_2 to yield a final concentration of 1% (refers to abstract, column 7 lines 17-67, column 8, column 9 lines 40-47, column 18, Example 4).

Regarding claim 6, the examiner asserts that a working concentration of hydrogen peroxide is of 0.5% to 3% w/v and the differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

According to the examiner, it would have been *prima facie* obvious at the time the invention was made to modify the method of treatment taught by MacDonald *et al.* with incorporating method step of treating the sample with an oxidizing agent and

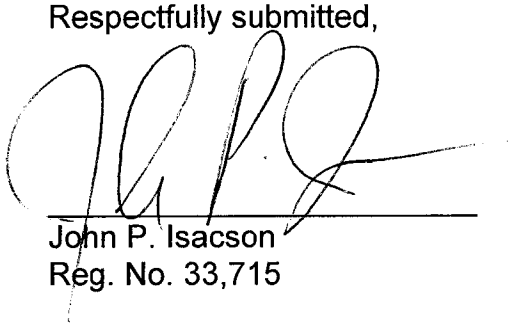
optimize the amount of the hydrogen peroxide as taught by Switchenko *et al.*

Applicants respectfully disagree with the examiner and refer to above clarification and arguments regarding MacDonald *et al.* Applicants indicate that MacDonald *et al.* does not disclose treatment of an endocervical fluid sample or a vaginal fluid sample, nor performing a diagnostic method on the sample in the presence of DNase. Switchenko *et al.* does not rectify the deficiencies of MacDonald *et al.* Accordingly, the combination of MacDonald *et al.* and Switchenko *et al.* does not make the amended claim 1 or dependent claims 4-6 obvious. Withdrawal of the obviousness rejection is therefore requested.

REQUEST

Applicants submit that claims 1-12 and 14-17 are in condition for allowance and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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Date

John P. Isacson
Reg. No. 33,715

PROSKAUER ROSE LLP
1001 Pennsylvania Avenue, N.W.
Suite 400 South
Washington, D.C. 20004
Phone: 202-416-6800
Fax: 202-416-6899

Customer No. 61263